

EXHIBIT D

KELLEY DRYE & WARREN LLP

A LIMITED LIABILITY PARTNERSHIP

WASHINGTON, DC
CHICAGO, IL
STAMFORD, CT
PARSIPPANY, NJ

**101 PARK AVENUE
NEW YORK, NEW YORK 10178**

(212) 808-7800

FACSIMILE
(212) 808-7897
www.kelleydrye.com

BRUSSELS, BELGIUM

AFFILIATE OFFICES
MUMBAI, INDIA

PHILIP D. ROBBEN
DIRECT LINE: (212) 808-7726
EMAIL: proffen@kelleydrye.com

September 16, 2008

VIA E-MAIL

Nicholas N. Paul, Esq.
Supervising Deputy Attorney General
Bureau of Medi-Cal Fraud & Elder Abuse
Office of the Attorney General
1455 Frazee Road, Suite 315
San Diego, California 92108-4304

Re: *State of California ex rel. Ven-A-Care v. Abbott Laboratories, Inc., et al.*,
Case No. 1:03-cv-11226-PBS (MDL 1456)

Dear Nick:

I am writing on behalf of Mylan, Dey, Schering-Plough, Warrick, and Sandoz (“Defendants”) in response to your August 29 letter containing California’s objections to Defendants’ Rule 30(b)(6) deposition topics (transmitted to you by letter dated August 19, 2008). We thought that a letter setting forth Defendants’ position on your client’s objections made sense prior to a meet and confer conference call.

Please note that your proposed deposition dates of October 21 to 24 are acceptable to Defendants. We are, of course, willing to work with you concerning the timing, duration, and location of the depositions to ensure that they go forward in an efficient manner. Also, we are aware that the deadline for California to file a motion for a protective order concerning Defendants’ 30(b)(6) topics is September 18. Defendants are agreeable to initially stipulating to a brief extension of this time – *i.e.*, seven to ten days – to allow meet and confer discussions to proceed on a reasonable schedule with the hope that motion practice can be avoided (or the scope of a motion at least narrowed).

Topics 1-17 and 63 (objected to in their entirety)

Notwithstanding California’s objections, these topics are appropriate subjects for a Rule 30(b)(6) deposition and the objections to them are not well founded. Topics 1 through 15

KELLEY DRYE & WARREN LLP

Nicholas N. Paul, Esq.
September 16, 2008
Page Two

seek testimony regarding the facts and circumstances forming the basis for the central factual allegations in California's First Amended Complaint ("Complaint"). Likewise, since the Complaint alleges Defendants deceived California by reporting "false and excessive prices," Topic 16 seeks testimony regarding what California contends these prices should have been and Topic 17 seeks testimony concerning whether California knew of the actual market prices for Defendants' drugs. Topic 63 seeks testimony regarding the basis for California's claim that it has been damaged and details about its purported damages. These topics seek testimony regarding California's basis for its purported causes of action against Defendants and, as such, are proper subject areas for a Rule 30(b)(6) deposition.

California's contention that these topics are "over-broad," "unduly burdensome," or an "unworkable attempt to hold a mini-trial" is not sufficient to foreclose testimony on them. Under Rule 30(b)(6), California is required, among other things, to designate a witness to testify on California's behalf regarding matters relevant to the claims and defenses in this action. Defendants' 30(b)(6) topics (particularly topics 1 through 17) are narrowly focused on California's allegations in this action. Defendants know of no precedent – and California does not cite to any – that would allow California to avoid producing a designee to testify concerning topics of this nature based on burden objections or based on vaguely stated objections that such a deposition would be "unworkable".

Similarly, California's contention that the designated topics are premature, because it is still waiting for discovery from Defendants, or because discovery is not completed, likewise misses the mark. First, California had at least ten years to conduct an investigation of the facts that underlie its claims. It is not reasonable for California, after such an extended period of investigation, to object to designating a witness on the basis that discovery is not complete. Second, and relatedly, Defendants' 30(b)(6) topics seek information concerning California's basis for the contentions in the Complaint, not every fact in a fully developed trial record that may ultimately support those contentions. As you know, Rule 11 requires that "factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery." Since none of the paragraphs from the complaint referenced in the 30(b)(6) topics were pleaded upon information and belief, California must have believed it had some evidentiary basis to support these allegations, and California is required to designate a witness to testify at least about those facts.

Nor can California rely on objections to these topics as "vague" or "ambiguous" or on the grounds that they "do[] not describe with particularity the matters on which examination is requested". The topics identify specific allegations made by California in its Complaint – often by quoting the language of the Complaint – and request a witness to testify to the facts that form the basis for those allegations. If these topics are not more specific about

KELLEY DRYE & WARREN LLP

Nicholas N. Paul, Esq.
September 16, 2008
Page Three

which facts they seek, it is because those facts are within the exclusive knowledge of California, not Defendants.

Finally, California's contention that these topics cover "questions of law" or matters protected by the work-product doctrine is mistaken. Defendants seek testimony concerning facts, not legal conclusions or attorney work product. In any event, an unsubstantiated assertion of privilege is not a sufficient ground to foreclose an entire 30(b)(6) deposition topic before any questions have been posed. The appropriate course is for California's counsel to object to questions which it believes implicate a privilege as they are asked, on a question-by-question basis, and make whatever instruction and record counsel believes is justified by the rules.

Topics 58-59 and 64-66 (objected to in their entirety)

California's objections to Topics 58 through 59 and 64 through 66 are equally unfounded. By alleging that it was defrauded by Defendants' conduct for an eleven-year period starting in January of 1994 and continuing through August 25, 2005 (the date the Complaint was filed), California put the time and manner in which it learned of Defendants' allegedly fraudulent conduct squarely at issue in this action. In particular, since Ven-A-Care filed the original *qui tam* complaint that commenced this action in 1998, and California contends that it continued to suffer injury as a result of Defendants' conduct for approximately seven more years, Defendants are entitled to seek discovery concerning what information Ven-A-Care provided to California, when it provided that information, and why California waited so long after the filing of the initial *qui tam* complaint to intervene and begin prosecuting this action. Moreover, California's knowledge concerning AWP and its continued reliance thereon as a reimbursement benchmark is entirely relevant to California's claims and Defendants ability to defend against those claims. Defendants are, therefore, entitled to deposition testimony on these topics.

Topics 58, 59, and 64 through 66 are stated with sufficient particularity and any burden California may face in preparing a witness to respond to them does not outweigh the Defendants' need to take discovery on them to defend this action. Moreover, California cannot avoid producing a witness on these topics by asserting privilege for the same reasons a privilege claim would fail as to Topics 1 through 17 and 63. Additionally, Defendants know of no attorney-client relationship between California and Ven-A-Care and its counsel, and California fails to cite anything which suggests that it may avoid discovery of entirely factual information provided to California by Ven-A-Care or its counsel on the basis of some type of privilege. In any event, California has waived any privilege it may have as to these matters by putting at issue in this action the time and manner by which it learned of the alleged fraud, and Defendants should be able to take testimony regarding those facts.

KELLEY DRYE & WARREN LLP

Nicholas N. Paul, Esq.
September 16, 2008
Page Four

Topic 54 (objected to in its entirety)

As for California's objection to Topic 54, we have a document that was produced by Alabama which purports to be a summary of the Pharmacy Reform TAG Meeting held on November 27 and 28, 1990. (A copy of the document produced by Alabama is attached to this letter.) The document identifies Mike Kneff from California as an attendee. In light of the fact that California is seeking damages from as early as 1994, we do not think that it would be unduly burdensome for California to take reasonable steps to inquire as to what knowledge Mr. Kneff or others may have of this meeting and designate a witness accordingly.

Topics 18-53, 55-57, 60-62, and 67-68 (objected to in part)

As for the topics on which California agreed to produce a witness subject to objections, California's objection to producing a witness who will testify on behalf of other state entities, or on behalf of California generally, on the grounds that Medi-Cal has suffered the injury and only officials from the California Department of Health Care Services ("DHCS") are suitable to provide testimony on those topics, is without merit. The State of California is the named plaintiff in this action, not DHCS, and the damages sought are sought on behalf of California, not DHCS. While it is possible that DHCS officials will be most knowledgeable about some of these topics, California cannot, consistent with Rule 30(b)(6), unilaterally limit the scope of the deposition to matters within DHCS' knowledge. It is California's obligation to produce witnesses who can testify as to matters within the knowledge of the State of California, regardless of which "state entity" may possess that knowledge. However, for the purposes of getting the depositions started, Defendants are willing to proceed with witnesses who could testify on behalf of DHCS on these points on the dates you propose in October, subject to and without waiving our right to seek testimony from witnesses who could testify on behalf of California, generally, at a later date.

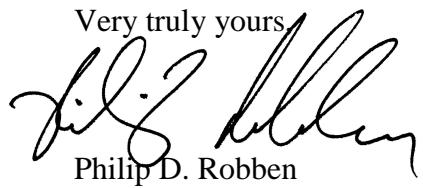
We believe that California's additional objections to these topics sounding in burden and vagueness, concerning the definition of certain terms, and asserting certain privileges can best be dealt with through negotiation prior to the depositions or through individual objections at the depositions themselves. Defendants are certainly willing to discuss them during a meet and confer conference.

* * *

KELLEY DRYE & WARREN LLP

Nicholas N. Paul, Esq.
September 16, 2008
Page Five

We propose to have a meet and confer conference call this week to discuss the issues framed by your August 29 letter and this letter. Please let me know a few times, if any, that work for you, and I will work with the other counsel on the defense side to try and schedule the call at a mutually agreeable time.

Very truly yours,

Philip D. Robben

PDR/dd

Attachment

cc: All Counsel of Record (via LNFS)

Attachment

Minutes of the November 27-28, 1990 Pharmacy Reform TAG Meeting



**STATE OF ALABAMA
DEPARTMENT OF ARCHIVES AND HISTORY**

624 WASHINGTON AVENUE • MONTGOMERY, ALABAMA 36130-0100

Mailing Address: P. O. Box 300100

www.archives.alabama.gov

EDWIN C. BRIDGES, Ph.D.
DIRECTOR

Director's Office	334-242-4441
Administrative Services	242-4361
Research Room	242-4435
School Tours	242-4364
Dev/Support Services	353-4594
Government Records	242-4452
Public Services	242-4363
State Records Center	242-4306
FAX	240-3433

CERTIFICATION

I, Edwin C. Bridges, do hereby certify that the accompanying 6 photocopied pages, embossed with the seal of the Alabama Department of Archives and History, constitute true and exact copies of documents from the Alabama Medicaid Agency, Commissioner's Office, Records of Administrative Heads of Agencies [box SG 20261] from original records on file in the Alabama Department of Archives and History.

A handwritten signature in black ink, appearing to read "Edwin C. Bridges".

Edwin C. Bridges
Director
Alabama Department of Archives and History
December 7, 2007

BOARD OF TRUSTEES

The Most Rev. Oscar H. Lipscomb, Chairman, **District 1** • James E. Simpson, Vice Chairman, • **District 6**

District 1: Vaughan I. Morrisette • **District 2:** Charles A. Stakely; Maury D. Smith • **District 3:** Fred D. Gray; Bernice B. Price

District 4: Bobby M. Junkins; Morris W. Savage • **District 5:** Joel T. Daves, IV; Shirley D. McCrary

District 6: Ocello S. Malone • **District 7:** June F. Davis; George P. Evans • **At Large:** Van L. Richey; Gillian W. Goodrich

Ex-Officio Member: Governor Bob Riley

*Commissioner
Herrmann*

STATE MEDICAID DIRECTORS' ASSOCIATION

**Summary -**

November 27 - 28, 1990 Pharmacy Reform TAG Meeting
Baltimore, MD

Attendees

Jerry Radke, Co-Chairman (PA)
Sanford Lugar, (NJ)
Sarah Mingledorff, (AL)
Jerry Wells, (FL)
Jim Peters, (OR)
Mike Kneff, (CA)
Gene Stephens, (KS)

Larry Reed, Co-Chairman, (HCFA)
Sandy Kramer, (MI)
Robin Colby, (OH)
Patricia Gladden, (TX)
Mike Yates, (RO IV)
Don Perkins, (RO VI)
Ean McLean, (RO IX)

Introductions/Welcome

Rozann Abato, Medicaid Bureau (MB) Deputy Director. Expressed appreciation that TAG members were able to come on such short notice. Characterized the pharmacy reform legislation as a challenge but stated that it will have to be implemented in a timely manner. There's a great deal of interest in this legislation from many sides. Everyone is interested and wants to meet with HCFA. HCFA will be meeting with manufacturers, pharmacist groups, regional offices. HCFA needs the input of the TAG which represents state experience. HCFA is committed to making the legislation work. Bill Hickman, Director of the Office of Medicaid Policy with the MB is in charge of implementation. Larry Reed will coordinate MB efforts to implement. David McNally, head of the Office of Medicaid Management will lead on issues of data collection, DUR format and electronic claims process.

Bill Hickman, Director, Office of Medicaid Policy welcomed TAG members and set out objectives for the meeting including: 1) consensus on the rebate agreement language, the MB wants state interests represented prior to meeting with manufacturers; 2) identification of the policy issues to be resolved; 3) consensus on working draft of DUR format; 4) consider and identify issues of reporting formats other than DUR (ex: HCFA's notice to states of agreements and drug prices); 5) time constraints, as states see it, on Point of Sale (POS) DUR.

There was a general discussion of the possibility of technical amendments. HCFA OLP indicated that there was only a weak possibility of technical amendments early in the next session of Congress. (APWA note: Senate finance staff are preparing for any early, "clean" technicals bill and requested APWA recommendations in early December. It is also our understanding that HCFA/MB officials met with Hill staff on December 3, 1990 and that staff from both houses met December 5, 1990 on technicals).

General discussion about the specs of the legislation. The MB clarified that after agreements are signed by March 1, 1991, states have until April 1, to add covered drugs or delete non-covered drugs. MB working assumption is that manufacturers will participate because many have expressed interest although generic manufacturers have expressed a number of problems with the legislation.

TAG Question: Are "expenditures" under Sec. 1927(a)(4) compared to WAC or AMP? How will MB evaluate state agreements if state 'expenditures' include dispensing fees and/or copayments? MB responded that these policy questions will need answers.

General discussion about the use of NDCs to report on drugs dispensed. TAG agrees that utilization should be based on claims payment date, not date of service.

TAG Question: To what extent will a manufacturer be responsible for rebates for retroactive eligibility? There was no answer to this question.

General discussion on manufacturer audit authority which raises client confidentiality issues and the desire of manufacturers to use utilization data for marketing purposes. The issue was raised of the chaos that could result from each manufacturer coming to audit each state each quarter. Providing the manufacturer with utilization data by zip code or other geographic delineation for use against manufacturer sales data to detect discrepancies and possibly assist in fraud detection.

General discussion on prior authorization, and coverage. TAG members expressed concern that the 24 hour PA response precludes a state from putting many drugs on P.A. PMA concerns that P.A. will be used by states to create formularies was also discussed.

TAG Question: Do states have to cover all package sizes and unit doses? General agreement that whatever is covered by the rebate agreement will be covered by the state.

TAG Question: Can states amend existing agreements since statute speaks to analysis of existing agreements as of date of enactment. There was no consensus on this.

General discussion of Generic Substitution. HCFA does not believe the new law changes current regulations concerning "dispense as written," "brand name medically necessary." The new law also doesn't change EAC or upper limits regulations. TAG members disagreed in that the new law stipulates that FFP can only be denied when generic

substitution is not done according to state law. MB commented that if states are correct, then savings will evaporate. (APWA note: Sen. Pryor will try to amend pharmacist reimbursement language to preclude reimbursement reductions).

General discussion on whether HCFA agreements will cover state-only drug coverage programs (for the elderly or general assistance). Many states get rebates for these programs too and do not want to lose the rebates. Further, a pharmacist can't distinguish between a Medicaid client and g.a. client with respect to covered and non-covered drugs. MB doesn't see how HCFA contracts can lock-in rebates for individual state programs. TAG recommended a two-tier contract structure so states can negotiate further for state-only program rebates.

TAG Question: Who will determine what company is the innovator? MB will rely on manufacturers.

General discussion of standard definition of "unit" since states use all different definitions. Also a discussion of OTCs, whether they are all included in the rebate agreement and what is the distinction between OTC and medical supply (insulin syringes, condoms, blood products).

General discussion that states want the HCFA rebate agreement to allow state agreements for items above and beyond Secretary's agreement. States expressed concern that there is a lot of information to be exchanged between HCFA, states and manufacturers in a short time frame.

TAG Questions: Whose responsibility is it to calculate the rebate amount? HCFA does not want to calculate rebate amounts. HCFA role is not to calculate but to validate.

General discussion of state's need to know both AMP and best price for policy reasons (to establish a pharmacist reimbursement baseline) and to calculate rebate amounts. HCFA is not clear the law allows sharing best price with states. HCFA will definitely share AMP information and actual rebate amount by NDC. Consensus is that MB should provide best price information but official decision has yet to be made.

General discussion of manufacturer audits. MB suggests that manufacturers agree to have their best price information independently audited prior to submission to MB. It was earlier discussed that the IG would audit manufacturers. States believe that manufacturers should agree on the one audit company to audit state utilization data.

General discussion on timing of rebates and reporting. Consensus that reporting and rebate payments be done on quarterly basis. Discussion of the fact that there is no penalty for manufacturers who do not pay the rebate in 30 days.

TAG Question: What if existing state contract sets the rebate period at something greater than 30 days, will FFP continue, can the contract be amended? No resolution.

General discussion on calculating rebate amounts. TAG members felt it was important for states to send utilization data calculated against NDC specific rebate amounts to manufacturers as an invoice. States felt that simply sending utilization data was insufficient since states would then have no idea how much to anticipate receiving. It was again agreed that states need rebate amounts from HCFA in a manner timely enough to generate an invoice.

Consensus to look at California contract language that calls for state audit of pharmacies where manufacturer sales data conflicts with state utilization data.

General discussion of state's ability to negotiate separate or complementary contracts. Consensus on ability to do both.

General consensus that when a manufacturer sells a drug to another firm, the original manufacturer with the rebate agreement remains responsible for rebate payments until the NDC is changed to reflect the sale.

General discussion of new drugs. MB believes it is the responsibility of the manufacturer to notify MB when a new drug is coming onto the market. There is consensus that the MB needs to define approved vs. approvable with reference to new drugs.

General discussion of MMIS issues lead by Rick Friedman, Director of MB Division of Payment Systems. MB wanted TAG consensus on the flow of information, work and responsibility between states and HCFA. MB also wants TAG to identify policy issues concerning both rebate agreements and data formats for rebate reporting. The TAG members expressed concern that there were other non-ECM issues that need resolution at this meeting and that since point of sale is not mandatory perhaps this item could be put off for another meeting. Dave McNally pointed out that prospective DUR cannot be achieved without point of sale. Most TAG members strongly disagree. Discussion on whether pro-DUR in the bill requires that pharmacist has access to a wide universe of client information. States disagree and feel pro-DUR requirements can be met by pharmacist using his/her own information.

General discussion on calculating rebate amount. General consensus that manufacturers should calculate actual rebate amount.

General discussion on whether manufacturer must rebate all drugs in order to participate or can they still participate while rebating only some products. General consensus that it is an all or nothing proposition.

General discussion of whether states can get info on actual rebate amount per drug. TAG reiterates the need. HCFA thinks that states should just send utilization data to manufacturer and manufacturer will calculate total rebate. States disagree.

General discussion of reporting formats. Consensus that states will send summary data to manufacturer either on floppy or hard copy. It was pointed out that there is less room for error if states submit electronically to manufacturers. Will send some information to HCFA via tape. TAG agrees to provide 9 digit NDC and number of units paid for. The 9 digit code will be used because HCFA will negotiate a rebate on all package size and units, so package size doesn't matter for reporting utilization. States will report all invoices on one tape to HCFA.

General discussion of common units. Decided that HCFA will define it. There is no disagreement within TAG on tablets as units. Aerosols, liquids and creams are another matter. TAG recommends that HCFA discuss this issue with pricing firms. Agreed that states will maintain their current unit systems and calculate rebates taking into account HCFA definitions of unit. States need to know HCFA's unit decision ASAP. HCFA will maintain a utilization master file with roughly 60,000 products on it. States are only to report where there is actual utilization.

General discussion on definition of best price. Consensus that best price is the lowest price in the country.

General discussion of nominal price and how to define it. Consensus that nominal price should be, 'with the exception of oral contraceptives and other products exempted by the Secretary, nominal price is anything less than 1% of AMP.'

General discussion of single award contract. Various opinions of what this is are expressed. Single award for any federal agency. TAG questions whether use of federal schedule is considered a single award contract? MB is not sure. TAG feels that use of federal supply schedule costs a very wide net of exclusion from AMP base and thinks these contracts included in AMP base would produce more savings. MB reminds TAG that this provision was included so that there was not a cost-shift from Medicaid to other federal agencies. Ultimately the Secretary will decide this issue in consultation with other federal agencies. TAG requests that a cost analysis of including or excluding federal supply schedule contracts include costs/savings to states through Medicaid.

General discussion of Point of Sale (POS) and Prospective DUR. TAG agrees that DUR means different things to different states. TAG generally feels that state laws apply to prospective DUR through patient counseling and state boards of licensing that review compliance. MB feels that status quo will not meet intent of the law. General consensus - states are not mandated to do POS and states comply already with pharmacist standards

through state licensure. Some states, even if they had on-line claims adjudication, would not do on-line prospective DUR because of client confidentiality issues and increased state liability.

General discussion of retrospective DUR (post-payment). General agreement that this mechanism can serve two functions 1) fraud and abuse which states already do, and 2) therapeutic DUR - some states get 50% FFP for this while others get 75% as an MMIS enhancement. Defining of terms - therapeutic duplication is checking whether client uses two of the same drugs at the same time (pharmacist should already do this); therapeutically-oriented DUR is deciding whether a specific drug should be used at all. Clarification that the law does not require a pharmacist to go beyond current scope of practice (no need to use on-line networked data base). States raise issues of client confidentiality and liability that exist in therapeutic DUR. Therapeutic duplication can be done through prospective DUR by pharmacist whether pharmacist is linked to on-line database or not. Therapeutic DUR relies on professional judgement of the pharmacist and on-line systems can't be the basis of therapeutic prospective DUR. Components of on-line real time claims adjudication: software and POS devise; standards for communications link between pharmacist and third party payor; third party payor software - the issue here is probably more financial than technical (if 30%-50% of all XIX claims are pulled out of the MMIS the fiscal agent will probably want to renegotiate the terms of the contract).

Benefits of on-time real-time claims adjudication: physicians can piggyback on the system; state administrative savings - studies have shown that POS is more expensive than systems with at least 50% paper or batch submissions; client benefits - clients generally don't care, they are not affected; benefit to pharmacists - these providers are really eager for an on-line claims adjudication system and are often willing to pay for it. On-line edits means no more after the fact denials. Discussion of what on-line claims adjudication system consists of. States discussed benefits of including client history file, on-line eligibility verification. In general, states felt it's hard to argue for the economic benefits of on-line claims adjudication but there's a clear benefit to providers that has to be considered.

TAG Consensus: The new law does not require on-line POS/ECM and there is no mandate for on-line prospective DUR. Intent of law is to move states to POS through permissive language.

HCFA Comments: MB does not have an articulated policy on ECM/POS with respect to MMIS funding. MB was thinking of encouraging on-line eligibility and prospective DUR through extending enhanced funding as a regular on-going policy. It is unclear how new law's specificity on funding and system components will affect HCFA thinking. Two years of 90% FFP for ECM is more restrictive than MB was thinking of going.

TAG Question: Would HCFA provide enhanced match if a state incorporates ECM into MMIS fiscal agent contract? MB response: Probably yes with the exception of hardware out in provider offices, including telecommunication costs. TAG pointed out that HCFA

pays for telecommunications costs in Calif., NY and Mass. eligibility verification systems. HCFA stresses that there is no official policy on this yet.

TAG recommends that HCFA put out a schedule specifying when POS demonstration requests will be accepted. Consensus that Systems TAG (under Sarah Mingledorff) will take the lead on POS/ECM. Work will include producing specifications on what level match is available for ECM and POS.

Review of Policy Issues

Whether MB will allow states access to information on AMP, best price and actual rebate amount. States want drug specific rebate amount information in a timely manner in order to produce manufacturer invoices. States want AMP and best price information at a later point in time since this information is not crucial to invoicing but is needed for policy reasons. TAG also recommends AMP information be sent to pricing services.

MB/Manufacturer Agreements. Agreements should include all manufacturer products. Agreements applicable to all states unless state has separate agreement. Manufacturer cannot pick and choose which products will be rebated.

State supplemental contracts. MB negotiates a master contract by which states must abide. States can negotiate supplemental contracts as long as state supplemental is consistent with federal statute. It remains unclear whether states have authority to negotiate separate contracts between November 5, 1990 (enactment) and January 1, 1991.

Lead time necessary to include or exclude drugs from state programs. No consensus or recommendations. Reiteration that states remain liable to lose FFP in the second calendar quarter.

Good faith efforts. TAG recommends that federal agreements include language on good faith efforts on the part of the manufacturers to rebate timely. Also recommended is language on conflict resolution between states and manufacturers.

Rebates on various package sizes. TAG recommends that MB negotiate one rebate amount for all package sizes in a product line. States will then only have to report utilization by the 9 digit NDC. AMP should be spread across (weighted average) all package sizes.

Definition of "Unit". TAG recommends that states continue to use their current definitions. State reports clearly identify what units are used. MB/Manufacturer contracts should clearly specify the units the manufacturer will report in. HCFA should consult pricing services to decide on unit definitions.

Best price. TAG recommends best price be lowest price.

Nominal Price. TAG recommends this be defined as a price that is less than 1% of AMP or exempted by the Secretary (exemption to include oral contraceptives).

Single Award Contract. TAG recommends that MB define this narrowly and that feds account for state Medicaid expenditures in any cost/benefit analysis used to define this term.

Definition of Over the Counter Drugs. TAG recommends MB decide how things like syringes, glucose test strips etc will be handled. TAG notes that if these are included as OTCs, more savings will be generated. TAG recommends that all OTCs that are prescribed should be rebated. Recommends that MB consult with FDA.

Outpatient v. inpatient, Drugs used "incident to." TAG recommends that all drugs billed as separate pharmacy claim be rebated. Claim must have NDC code, not HCPCS.

Prior Authorization. Consensus that states can PA all drugs but new drugs. No consensus on whether state can specify mode of PA request. Consensus that PA request can come from anyone. MB thinks that Secretary will continue to let states define "emergency situation". General consensus that law intends 'emergency situation' as administrative convenience (ex. PA request received at 4:00 p.m. on Friday, effectively means that a 72 hour prescription must be permitted).

Audits. Consensus that HCFA/IG will audit manufacturers. TAG recommends that manufactures be required to arrange for one audit company to serve as auditor for all states. TAG sees two types of manufacturer audit requests - 1) to verify state system to report unit utilization (an SPR-type activity), and 2) a look-behind at actual claims to review accuracy of pharmacy reporting. TAG agrees that look behind activity should lead to state audit of individual pharmacies.

Analysis of existing state agreements to see if they meet or exceed HCFA agreements. TAG recommends that MB define state expenditures to exclude dispensing fees and adjust for differences between WAC and AMP (if state contract is based on percentage of WAC). Analysis of state expenditures should look at cost of goods (exclude co-pay, dispensing fees, AWP minus percentage). Compare apples to apples.

DESI drugs. TAG recommends that covered outpatient drug definition exclude DESI drugs.

Payment for drugs available free through other sources. Can states remove drugs that are available at no-charge from other sources (PHS for examples) from Medicaid formulary? Unresolved.

Wrap-Up. HCFA will redraft rebate agreement within short turnaround. Will seek answers to unresolved policy issues/questions. Requests that other issues be sent to MB on an on-going basis.

TAG recommends that MB meet separately with various interests including manufacturers (including PMA, Merck, NAPM); pricing services; pharmacists (APhA). TAG also recommends that there be a meeting of a subset of the Systems TAG to discuss POS in January and that this meeting include representatives from National Council of Prescription Drug Programs, the American Society Association of Automation in Pharmacy, and the Private Sector Group. TAG recommends that Pharmacy Reform TAG meet again to discuss post-payment DUR and that this meeting include Iowa which has a long standing retrospective DUR system.